

KORA DAILY SAFE 80- hand sanitizer gel gel
Kora Holdings LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

For hand sanitizer to reduce microorganisms that potentially can cause diseases. Recommended for repeated use.

Warnings

For external use on hands only. Flammable. Keep away from fire or flame

Do not use

- in or near the eyes. In case of contact with eyes, rinse eyes thoroughly with water.

When using this product do not use in or near the eyes. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation, swelling or redness develops.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

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Directions

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using.

Other information

- Store below 110°F (43°C)

Inactive ingredients

glycerin (Glycerol), hydrogen peroxide, Sterile Distilled Water

Package Label - Principal Display Panel

500 mL NDC: 75504-080-01

KORA DAILY SAFE 80			
hand sanitizer gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75504-180
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 mL in 100 mL
Inactive Ingredients			
	Ingredient Name	Strength	
	GLYCERIN (UNII: PDC6 A3C0 OX)	1.45 mL in 100 mL	

HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75504-180-11	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/20/2020	

Labeler - Kora Holdings LLC (695692001)

Establishment

Name	Address	ID/FEI	Business Operations
Sellus		690026575	manufacture(75504-180)

Revised: 4/2020

Kora Holdings LLC